

REMARKS

Claims 1-16, 20-26, 28 and 53-55 have been amended. 1-32 and 53-55 are presently pending in the application.

I. INDEFINITENESS REJECTION

The Office Action rejected claims 11, 12 and 18 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Regarding this rejection, Applicants submit that certain, preferred membranes, according to the increasing-thickness aspect of these claims, can be heated to their glass transition temperature and then stretched or otherwise “shaped” from a natural (i.e., pre-shaped) configuration to a contrived or loaded shape. The shaping cannot occur below the glass temperature (because it is not pliable or moldable) and cannot be performed at or above the melting temperature (because it loses its memory whereby such shaping would be permanent). The material is then held in its “shaped” configuration and allowed to cool, so that it retains the new shape. Subsequently, such as at a time of implantation of the membrane, it can be brought to its glass transition temperature at which time it will, under its own memory, return to the pre-shaped configuration.

Paragraphs 0035 and 0036 of Pub. US07/0116739 state that this process may be advantageous in situations where a specific configuration or size is desired for the implantation of the membrane. According to a typical implementation, a membrane having a first thickness is stretched down to a second, smaller thickness so that when the processed and sterilized membrane is subsequently brought to its glass transition temperature its thickness can return back to the first thickness. Incidentally, Paragraph 0043 of Pub. US07/0116739 also states, for instance, that a preferred thin membrane of the present invention comprises a substantially uniform composition of an amorphous polylactide, for example PLLA, and paragraph 0046 of

the same document adds that PLLA has a glass transition temperature of about 55° Celsius and a softening-point temperature of about 110° Celsius.

II. PRIOR-ART REJECTIONS

Regarding the prior-art rejections, the Office Action rejected claims 1-5, 15-17 and 19-32 as being unpatentable under 35 U.S.C. § 103(a) over Totakura et al. (U.S. Patent No. 5,795,584), Vyarkaram et al. (U.S. Patent No. 6,333,029) and Tang et al. (U.S. Patent No. 5,412,068), and rejected claims 6-10, 13 and 14 as being unpatentable under 35 U.S.C. § 103(a) over Totakura et al., Vyarkarnam et al. and Tang et al. as applied to claims 1-5, 15-17, and 19-32, and further in view of Lemperle et al. (U.S. Patent No. 6,391,059), Lemperle et al. (U.S. Patent No. 6,280,473), and Mansmann, K. (U.S. Patent No. 6,530,956). Applicants respectively disagrees with these rejections.

A. ALLEGED ADMITTED PRIOR ART

Initially, Applicants would like to respond to particular remarks set forth in the outstanding Office Action, many of which would appear to indicate inadvertent misunderstandings or mischaracterizations of the invention and its relation to the prior art.

For instance, a cornerstone of the outstanding Office Action's prior-art rejections appears to be founded upon a perceived existence of Admitted Prior Art in the current application (cf. Office Action, pages 2 and 3). Regarding this allegation of an admission, it is without merit, as evidenced by the current amendments to the Detailed Description which are submitted herewith and which were approved by Examiner Timothy E. Betton in the Examiner Interview conducted on March 17, 2008 with the undersigned representative.

B. INSUFFICIENCY AND UNINTELLIGIBILITY OF OBVIOUSNESS REJECTIONS

Furthermore, attention is directed to the Office Action's apparently hindsight-based listing of prior art abstracts and conclusory, confusing commentary that:

[i]t would be *prima facie* obvious to ... recognize with a reasonable expectation of success via the combining and/or incorporating together the methods and compounds of [references] with the teachings of [references] said references encompass the central elements of claimed invention as explained above. The motivation to combine is present in Totokura et al. which encompasses elements of Vyarkarnam et al. Vyarkarnam et al., in addition, teach elements that are not readily disclosed within Totokura, but encompass further elements obvious over instant claims and subject invention. Tang et al. contains elements of both Totokura et al. and Vyarkarnam et al., but with additional elements that fully encompass elements of claimed invention. Lemperle et al. and Mansmann et al. are the motivation to further combine by encompassing the specific claim limitations of instant claims 6-14.

Regarding this language, it is unintelligible and cannot be comprehended. The Examiner should heed Section 706.02(j) of the Manual of Patent Examining Procedure (MPEP), which is entitled "Contents of a 35 U.S.C. 103 Rejection" and which is reproduced below:

35 U.S.C. 103 authorizes a rejection ...the examiner should set forth...(C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification ... there must be some suggestion or motivation...to modify the reference or to combine reference teachings...[and the teaching or suggestion...must ...not [be] based on applicant's disclosure...the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious...It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply...it

is important that the written record clearly explain the rationale for decisions...including a discussion of the requirements of *Graham v. John Deere*....

Applicants respectfully submit that the prior-art rejections of record would appear to be incomplete, and also unintelligible. The Office Action's juxtapositioning of disjointed abstracts/text corresponding to SIX patents (an unreasonable number), concluded with the above paragraph, does not provide: all of the differences in each of the rejected claims over the applied references, the proposed modifications or applications of each of the applied reference necessary to arrive at each of the claimed combinations, and explanations of why one of ordinary skill in the art at the time the invention was made would have been motivated to make each of the proposed modifications.

Applicants request that the Examiner present an unintelligible line of reasoning as to why the artisan would have found each of the claimed combinations, beginning but not limited to those of the independent claims, to have been obvious in light of the teachings of the references. Moreover, each teaching or suggestion to make each claimed combination and the reasonable expectation of success, once provided by the Examiner, must be (i) found in the prior art and (ii) not based on hindsight from Applicants' disclosure.

The examiner is also requested to properly communicate the relevance of each of the relied-upon prior-art references and how, structurally and functionally, they interrelate, so that the issues can be identified early and the applicant can be given fair opportunity to reply. As set forth in the above text from the MPEP, it is important that the written record clearly explain the rationale for the Examiner's rejections.

Applicants further request that the criteria of Graham v. John Deere be laid-out in each of the rejections along with an application of those criteria for each of the rejections.

C. NON-OBVIOUSNESS OF CLAIMED INVENTION

Features of the present invention are synergistic, and were not arbitrarily thrown together from a laundry list of attributes. The unique combinations include the provision of a simple-to-make (e.g., from simple compositions/reactions; cf. Pub. US07/0116739, par. 0007 and 0008) anti-adhesive membrane that offers reduction in both chemical tissue inflammation (e.g., the membrane is ultra-thin, for less inflammation during resorption; cf. Pub. US07/0116739, par. 0051) and mechanical tissue inflammation (e.g., non-leaking barrier, smooth, non-porous, cf. Pub. US07/0116739, par. 0047 and 0050; yet strong enough to have value and versatility; cf. par. 0031 and 0032, 0043). Relatively high inherent viscosities facilitate manufacture/handling of the fragile, ultra-thin membranes (cf. par. 0010, 0031, 0032). Thick edges or other thickened areas facilitate suturing/welding/bonding/folding of the fragile, ultra-thin membranes (cf. Pub. US07/0116739, par. 0041, 0045, 0046). Pre-implantation automatic reshaping at glass transition temperatures (i.e., biasing) facilitates transport, shaping and positioning of the fragile, ultra-thin membranes (c.f. Pub. US07/0116739, par. 0035 and 0036).

Thus, multiple points of novelty are presented, corresponding to multiple ranges of values. For example, a claimed range of thicknesses of about 0.001 mm to about 0.300 mm does not mean that all values in the range are admitted interchangeable or equivalents. Rather, it means that Applicants' attorney has advised that very broad ranges be provided in certain places of the application to prevent easy design-around activities by competitors seeking to copy, in this example, other aspects of the invention such as the inherent viscosity range or the biasing aspect. In other words, as an example, a claim directed to multiple, independently-novel features should be drafted with the broadest ranges (not the narrowest) for each of those features. Regarding thicknesses, continuing with the instant example, the broad range is provided in the independent claim but then more preferred ranges are recited in the dependent claims. It is described in Applicants' specification that preferred thicknesses are 0.015 mm to about 0.025 mm (c.f. Pub. US07/0116739, par. 0038). Indeed, an actual product corresponding to this

invention is sold under the name of SurgiWrap, indicating its extremely thin construction. Due to its thin architecture, other aspects were developed to enhance its strength.

One such feature is to form the membrane from a polymer having a pre-formation inherent viscosity that is relatively high. Again, while the independent claims contain relatively broad characterizations of the inventive inherent viscosity, these characterizations were, again, broadly recited upon the advice of counsel to facilitate the blockage of competitors' activities seeking to easily design-around the claimed invention; more preferred ranges are recited in dependent claims and are described in Applicants' specification (c.f. Pub. US07/0116739, par. 0031 and 0032).

Another such feature, implemented for reasons including the membrane's thin architecture, is to form the membrane with molecular bias(es).

A further feature is to form the polymermic material with thick portions for facilitating one or more of strength (e.g., as a rib), suturing capability (e.g., less tearing), and heat bonding capacity (e.g., wherein polymer of the thick portion is induced to flow to facilitate heat welding or bonding).

Now, regarding the Office Action's citation of prior-art references in the claim rejections, the Examiner has cherry-picked arbitrary elements from arbitrary patents and tried to make them all fit into one implant with no logic being used as a binder. Reasoning and motivation for such combinations must be present and is essential, but is lacking. Accordingly, Applicants maintain that the claimed invention is neither anticipated nor obvious in view of any of the prior-art references of record, taken separately or together, in any combination, either in structure or in process. In particular, Applicants wish to, and hereby do, now introduce into the record the following:

- (1) Totakura et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1), and a thickness of about .001 mm to 0.300 mm (claims 1 and 25);
- (2) Vyarkaram et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1);
- (3) Tang et al. fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1);
- (4) Lemperle et al. (059) fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1), and a thickness of about .001 mm to 0.300 mm (claims 1 and 25);
- (5) Lemperle et al. (473) fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), and non-porosity (claim 1); and
- (6) Mansmann, fails to disclose or teach: adhesion-inhibition (claims 1 and 25), biased molecular orientation (claim 1), an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL (claims 1 and 25), smooth surfaces (claims 1 and 25), non-porosity (claim 1); and a thickness of about .001 mm to 0.300 mm (claims 1 and 25).

Contrary to the Examiner's interpretation of Lemperle et al. (059), column 14, lines 1 and 43 of Lemperle et al. (059) do not come close to teaching, or even suggesting, by any stretch, a "molecular orientation in regard to a single axis or axes (at least two)" (cf. Office Action, page 8). Instead, the referenced lines 1 and 43 disclose an axis load of a cylinder and a direction (axis) along which corrugations are disposed, respectively.

As for the reliance of Lemperle et al. (059) for "teach[ing] specific additives ... which [makes it] obvious," the Examiner must realize that he is not charged with examining each claim limitation separately, but rather, each claim must be searched, considered, and examined as a whole.

Even if, hypothetically, limitations could be examined separately, it can be seen from the above listing that none of the above list of references disclose or suggest an "adhesion-inhibition membrane."

Furthermore, even if, hypothetically, limitations could be examined separately, it can be seen from the above listing that none of the above list of references disclose or suggest a "an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL."

It is well established that a claim can be rejected on obviousness grounds only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior-art reference or combination of prior-art references. As set forth in Section B. above, for a rejection under 35 U.S.C. 103(a) to be proper, every limitation recited in the claim being rejected must be disclosed/evident in/from the collection of prior-art references. In the instant case, Applicants respectfully submit that the cited references neither disclose nor suggest each and every element that is recited in the rejected claims. For instance, the recitation of an "adhesion-inhibition membrane...exhibiting an anti-inflammatory characteristic with a viscosity property greater than about 1 g/dL" is not disclosed in any of the references. Since it is in none of the "parts," it certainly cannot be in the resulting "whole."

With respect to the claims not specifically mentioned above, it is submitted that each of these claims is likewise free and clear of the scope of the cited references to similar and even greater degrees, not only by virtue of its dependency upon the respective base claim but also for the totality of features recited therein.

Accordingly, the outstanding rejections under 35 U.S.C. § 103(a) are improper and need to be withdrawn.

D. ALLOWABLE CONTENT OF CLAIMS 53-55

On a related topic, the Examiner's attention is directed to claims 53-55. In particular, while not agreeing with the above rejections, Applicants would like to thank Examiner Timothy B. Betton for his thorough search and review of the prior-art, his careful consideration and examination of the present application and claims, and his apparent indication by implication that these may contain allowable subject matter. More specifically, it would appear that the thickness-transitioning limitations of claims 53-55 were not addressed in any prior-art rejections. Accordingly, Applicants interpret such to an allowability-indication by implication, as Applicants understand, corresponding to the non-discussed limitations of claims 53-55 being construed as containing allowable subject matter.

Regarding the apparently favorably-considered subject matter, paragraphs 0035 and 0036 of Pub. US07/0116739 state that the thickness-transitioning feature of the current invention "may be advantageous in situations where specific configurations and sizes are desired for the implantation of the membranes." As discussed above, Applicants' Detailed Description describes how, according to a feature of the invention, shrinkage can be selectively controlled when the membrane is heated, for controllability in situations where specific configurations and sizes are desired in connection with implantations of the membranes. In a particular implementation, a membrane extruded through an orifice with a first thickness is subsequently **stretched** down to a second, smaller thickness. The first thickness can be greater than two times, or five times, the second thickness, and more preferably greater than ten times the second

thickness. When the processed and sterilized membrane is subsequently brought to its glass transition temperature, its thickness **returns back** to the first thickness.

Applicants submit that ~~that~~ this claimed thickness-transitioning feature is nowhere disclosed or suggested in the prior art of record, and, thus, claims 53-55 are allowable over the prior art of record.

E. CONCLUSION

Accordingly, it is respectfully submitted that all of the current claims in the subject application distinguish over, and are allowable over, the prior art of record. Reconsideration and withdrawal of all rejections of record is respectfully requested.

In view of the above, Applicants believe that the application is now in condition for allowance, and an early indication of same is requested. The Examiner is invited to contact the undersigned with any questions

Respectfully submitted,



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